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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,826	02/09/2004	Barry N. Gellman	MIY-P03-006	9242
28120	7590	08/11/2008		
ROPES & GRAY LLP PATENT DOCKETING 39/41 ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER LACYK, JOHN P	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 08/11/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/774,826

**Applicant(s)**

GELLMAN ET AL.

**Examiner**

John P. Lacyk

**Art Unit**

3735

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 163-171, 173-180, 182-188, 190-198 and 200-206 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 163-171, 173-180, 182-188, 190-198 and 200-206 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Applicant's arguments, filed 07/07/08, with respect to the prior art rejections have been fully considered and are persuasive. The final rejection of claims 163-168, 170-171, 173-180, 182-188, 190-198, 200-206 has been withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 163-168, 170-171, 173-180, 182-184, 186-187, 190-198, 200-206 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 163, 190, 200 recite that the pouch covers only partially the sling, however there is no support in the originally filed specification to support language that the pouch covers only partially the sling. Claims 165-167, 193-195 disclose the shaft having a channel located at the distal end, however the specification as originally filed lacks proper support for the shaft having a channel, the only place a "channel" is recited is in regard to Figure 92, referring to a channel (1818) in tissue (62) and not to a channel on the distal end of the shaft. Further claims recite that the "channel is releasably lockable" however there is also no support for the "channel" being releasable. With regard to claims 175 the claims recite an "interlocking mating structure" between the shaft distal end and the sling assembly, however the only

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recitation in the specification for anything "interlocking" is the first and second handles. Therefore the specification lacks proper support for the shaft and sling assembly having an interlocking mating structure.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 175-180, 185-188, 193-198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benderev et al (5,439,467) in view of Norris et al, "Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach".

Benderev et al discloses a device for treating incontinence having a shaft that has a curved portion and a distal end (Figures 1 and 1a; column 2, lines 34-36 and column 5, lines 7-9) and a "sling assembly" or suture for being received in the distal end of the shaft. Benderev et al teaches the claimed system except for the "sling assembly" specifically being a flat shape. Norris et al teaches a sling assembly for use in treating incontinence and teaches that it is well known to use a sling that has a flat shape (see Figure 2 and column 2 under "Technique"). A modification of Benderev et al such that the suture used as a sling is substituted with a flat shaped sling as taught by Norris et al would have been obvious to one skilled in the art since the flat shaped sling would provide more surface area to allow for added support to treat incontinence. Therefore a modification of Benderev et al would have been obvious since this would be the mere

substitution of one known type of sling to treat incontinence for another and would allow for added support and a more evenly distributed force on the body. Benderev et al further teaches the use of a channel (130) on the distal end of the shaft (Figure 2) the is used to attach to the suture in a releasable manner that can be locked or unlocked (column 5, line 60-column 6, line 36). This is considered to be a "interlocking mating structure" between the shafts distal end and the suture or sling assembly.

Claims 163-168, 170-171, 173-174, 182-184, 190-192, 200-206 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benderev et al in view of Norris et al as applied to claims above, and further in view of Wilkinson et al (3,580,256).

Benderev et al and Norris et al teach the claimed device except for the use of a pouch over a portion of the sling assembly.

Wilkinson et al. teaches the use of a pouch or sheath with a sling material (as seen in Figures 1 and 7) to protect the body from the sling, wherein the pouch or sheath is flexible and can lay in a substantially flattened configuration (as described in lines 55-65 of column 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pouch similar to that taught by Wilkinson et al. over a portion of a sling assembly similar to that taught by Benderev et al and Norris et al because pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (571)272-4728. The examiner can normally be reached on 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.P. Lacyk

/John P Lacyk/  
Primary Examiner, Art Unit 3735